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(54) **CONTINUOUS AMBULATORY PERITONEAL DIALYSIS CLAMPING SYSTEM.**

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Description

Background of the invention

This invention relates to a connector system, and more particularly, to a system for use in peritoneal dialysis generally.

Specifically, continuous ambulatory peritoneal dialysis (CAPD) is an increasingly popular form of dialysis. CAPD employs a bag of sterile peritoneal dialysis solution which is opened through a pierceable membrane. The bag is connected to a patient's peritoneal cavity through a tubing set which includes a membrane-piercing spike. In order to perform dialysis, fresh solution in the bag is drained into the peritoneal cavity and remains in the cavity for the dialysis or dwell period, usually four to six hours. At the end of that period, spent dialysis solution is drained from the cavity back to the bag. Then a second bag of fresh solution is exchanged for the bag of spent solution, is connected to the tubing set, and the cavity is filled with fresh solution and the dialysis process repeated.

One of the principal areas of concern in peritoneal dialysis generally is that the connection between the tubing set and the dialysis solution bag must be kept sterile, particularly when the bag membrane is pierced in order to drain the solution from the bag to fill the peritoneal cavity.

Ultraviolet (UV) sterilization is a desirable form of sterilization for use in a peritoneal dialysis procedure, particularly CAPD.

It is an object of this invention to provide such a connector system which can be UV-sterilized and easily used by a patient.

US—A—3986508 discloses a connector system for use in processing blood. The connector system is sterilisable by ultraviolet radiation, or other means, and includes a transfer spike on the end of a transfer tube and a delivery tube closed with a pierceable membrane. The connector system includes a housing member, a collapsible, tubular sheath member having an opening at one end of the housing member for receiving the spike and an opening is provided at the other end of the housing member for receiving the delivery tube. The sheath member is expansible and collapsible to hold the spike in spaced relation to the pierceable membrane in the expanded position and to allow the spike to penetrate the pierceable membrane in the collapsed state. The pre-characterising clause of Claim 1 is based on this disclosure.

US—A—3685795, US—A—4080965 and US—A—4056116 all disclose valves suitable for connecting sterile containers or other sterile members in which a hollow spike is movable to pierce a membrane and in which the spike and the membrane are mounted in a housing which itself is collapsible. In US—A—3986508, the collapsible sheath member is separate from and is mounted within the housing.

Summary of invention

The present invention is characterised by clamp means carried by the housing member for retaining and closing the delivery tube, the clamp means including a portion of the housing member, which portion defines the opening for receiving the delivery tube and has a transverse channel, the clamp means further comprising a slide slidable in the channel, the slide having a slot for receiving the delivery tube and being movable within said channel between tube-closing and tube-opening positions; whereby the delivery tube may be inserted into the sheath member and held in a position to be pierced by moving the slide to the tube-closing position, and said transfer spike may be inserted into the sheath member, held for ultraviolet treatment, and then thrust into the delivery tube to pierce the membrane associated therewith and provide a sterile condition.

Flow control slide clamps are known in the medical field and US—A—2889848 discloses a flow control clamp which has a body with an elongate slot receiving a flexible tube, the slot having converging edges. A slide is provided to hold the tube. Relative movement of the slide and the body causes constriction of the tube in one direction and release of the tube in the opposite direction, to control fluid flow through the tube.

Using the connector system of the invention, a dialysis solution bag delivery tube may be inserted into the sheath member through the housing end, and held in a piercing position by moving the slide clamp to the closing position. The transverse spike may be inserted into the sheath at the other end and held for application of ultraviolet light. After the ultraviolet application, for antibacterial effect within the sheath, the spike is thrust into the dialysis solution bag delivery tube to pierce the membrane which closes it, to provide a sterile connection between the spike and the tube so that the liquid can flow between the solution container and the peritoneal cavity of a patient.

A casing member, which retains the transfer spike either in piercing or nonpiercing position, may comprise a pair of hinged halves having grooves at each end which are proportioned to grasp clamping shoulders or flanges positioned at opposed ends of the collapsible sheath member, to hold the sheath member in an open position, or alternatively to grasp one end of the collapsible sheath member and a flange or clamping shoulder on the spike, to hold the system in collapsed, membrane-piercing relation.

Other details of the invention are as shown in the drawings and specification below.

Brief description of the drawings

Figure 1 is a diagrammatic view showing the solution bag, the connector, the tubing set, the catheter, and the patient;

Figure 2 is an exploded perspective view showing the spike and the connector of Figure 1;

Figure 3 is a sectional view showing the con-

nector with the spike of Figure 1 in the non-piercing sterilization position;

Figure 4 is a sectional view similar to Figure 3 showing the connector with the spike in the pierced position;

Figure 5 is a sectional view taken along line 5—5 of Figure 3 and showing the slide clamp grasping the tube end;

Figure 6 is a fragmentary transverse sectional view taken along line 6—6 showing the slide clamp in the non-grasping position;

Figure 7 is a perspective view of the slide clamp showing notch-like surface recesses for folding of the upper clamp section relative to the lower clamp section; and

Figure 8 is a side elevational view of the clamp in the folded position with the "clam-shell" retainer in position.

Description of the preferred embodiment

Referring now to Figure 1, peritoneal dialysis solution bag 10 which has a short delivery tube 11, is shown coupled to a patient 12 through catheter 14, tubing set 16, and connector 18. The tubing set 16, which is replaced perhaps once a month, includes a length of tubing 19, a catheter coupler 20 for connecting the tube set to the catheter, and a transfer spike 24. If so desired, a filter may be included in the tubing set.

The transfer spike 24 and connector system 18, which includes sheath and housing member 26 and slide clamp 28, are shown in Figure 2. Spike member 24 has a central bore 29, a tubing set connecting end 30, a round clamping shoulder 32; a handle or grasping center section 34 which includes a round disc-like member 36; and a hollow piercing or spiking point 38 having liquid flow ports 40 which communicate with bore 29.

The sheath and housing member 26 includes a hollow spike-receiving sheath member 42, and a slide-receiving housing 44. The spike-receiving section 42 is hollow and tubular, having an accordion-like shape, and is collapsible. Section 42 includes a spike-receiving aperture 46, hexagonal clamping shoulder 48, and convoluted, collapsible, ultraviolet transparent section 50. Second tubular section 52 and second hexagonally-shaped clamping shoulder 54 are also provided. Collapsible section 50 may be made of an ultraviolet transparent plastic such as polyethylene or other desired plastic, preferably selected and formed so that at least 15 percent of the ultraviolet radiation to which it is exposed passes into its interior for sterilization therein.

Slide housing 44 may be integral with sheath member 42, being connected thereto adjacent to clamping shoulder 54. Housing 44 may be rectangularly shaped, having a transversely oriented slide-receiving slot 56 extending through its central portion, and a pair of stepped stop ledges 58, 60. Slide clamp 28 is insertable into slide housing 44 from either end of slot 56, with leg 67 on either the right or left side of slot 56.

Housing 44 includes a delivery tube-receiving opening 61 which is aligned with tubular member 52 and is best seen in Figure 4.

Slide member 28 is a bifurcated, fork-like member having a bight or head section 62 that includes a downward movement-limiting shoulders 64 which cooperate with the stops 58, 60 in limiting the movement of the slide member relative to the housing. A pair of mirror image shaped legs 66, 67 extend from the head section 62. The outer surface of each leg 66 and 67 includes outwardly tapering, shoulder-like intermediate portions 68, and limit shoulders or hooks 70 for limiting upward movement of the slide clamp. The legs 66, 67 are shaped so as to form a thin slot 72 extending from head section 62 downwardly toward an enlarged tube-receiving opening 74. A tapered tube-guiding section 76 connects slot 72 and enlarged opening 74. It will be noted that the shoulder portions 68 are positioned slightly above opening 74, and this provides some spring bias to the slide clamp so as to maintain its position in the housing when the slide is in an upper position where limit shoulders 70 engage the slide housing.

Each of limit shoulders or hooks 70 may define tapering ramp section 70a which permits insertion of the slide into slot 56. Hooks 70 can engage the lower edges of the housing 44 so as to limit upward movement of the slide clamp. Hooks 70 also can provide alignment of opening 74 with housing aperture 61 and sheath tube 52 when they engage the lower edges of housing 44.

A "clamshell" retention casing 78 is provided for positioning spike 24 relative to clamp 28. Casing 78 has two hingedly-connected half sections 80 82 which may be substantially identical, except that section 80 includes tongue-like members 84 and section 82 includes latch-like members 86 for locking cooperation with members 84. Each section includes end wall formations 87, 88, that define grooves 90, 92 which can receive hexagonally-shaped clamping shoulders 48, 54 on the sheath, and round shoulder 32 on the spike to immovably retain the system in connected relation.

Referring now to Figure 3, spike member 24 is shown in a non-piercing sterilization position. As can be seen, casing 78 is shown holding the collapsible portion 50 of the sheath in an expanded position, with shoulders 48, 54 being held in grooves 92 and 90 of the casing 78, respectively. With this arrangement, piercing spike 24 can be inserted into the sheath, but it cannot pierce the delivery-tube membrane 11a that prevents flow through tube 11 of bag 10, which is inserted into tube 52 at one end. Tube 11 is shown being held in position by slide clamp 28, which has been pressed downwardly so as to grasp and close tube 11 in slot 72. As shown in Figure 3, pierceable membrane 11a is still sealed. The piercing or transfer spike 24 is inserted into sheath member 50, but by virtue of the casing 78 it is prevented from piercing the

membrane 11a.

Figure 5 shows tubing clamp 28 holding tubing 11 in the grasping position shown in Figure 3.

After connection of the parts, clamshell casing 78 can be removed, and sheath section 42, carrying tube end 11, membrane 11a, and spike 24 may be placed in an ultraviolet sterilizer. After appropriate sterilization with ultraviolet light, spike 24 is then thrust through membrane 11a so as to pierce the membrane, to permit fluid flow from bag 10 through spike 24 and from there to the patient.

Referring now to Figure 4, hollow point 38 of spike 24 is shown thrust through membrane 11a, and slide clamp 28 is then raised to the non-grasping, flow permitting position shown in Figure 6.

Once spike 24 has been thrust through member 11a, casing 78 is then reapplied to hexagonal shoulder 54, and round shoulder 32 on spike 24 as in Figure 4. This holds the spike in a fluid flow position so that fresh solution can flow from the bag through the spike to the patient with hollow point 38 holding tubing 11 in position by friction. After the peritoneal cavity is filled, clamp 28 is moved to its sealing, grasping position to close off tube 11. Casing 78 can remain attached and clamp 28 can remain in closed position throughout the dwell period of the dialysis solution in the peritoneal cavity until it is time to drain the cavity of spent solution and to exchange solution bags.

Referring now to Figures 7 and 8, slide clamp 28 includes a pair of transverse lines of folding weakness 65 which permit folding of the clamp to minimize its size and facilitate its concealment by the patient during use. As seen in Figure 7, the lower section 28a of clamp 28 may be folded transversely along the fold lines 65 to a position at right angle with the upper section 28b. The folding relative to clamshell casing 78 is shown in Figure 8, with section 28a being bent over toward casing 78, and with tube 11 in closed, no-flow position. This folding feature may be used in the solution dwell portion of dialysis.

Integral flexible strap 96 on clamp 28 limits the spreading of legs 66, 67 to assure the sealing of tube 11 when placed in slot 72. In operation, slide clamp 28 is inserted into slide housing 44 by aligning clamp 28 with housing slot 56 and then pushing clamp 28 downwardly.

The clamp entrance ramps 70a engage the edges of slot 56 to bias the clamp legs inwardly and permit them to enter the housing. Clamp 28 is pushed downwardly until the hooks 70 emerge from the other end of the slot 56, and legs 66 and 67 then snap outwardly and engage the inside walls of the slot. Hooks 70, in cooperation with the housing provide an upward movement limiting means with clamp opening 74 being aligned with sheath opening 61.

In use, delivery tube 11 of a bag 10 is inserted into housing 44, and clamp 28 is then pushed downwardly to grasp and close tube 11 in slot 72. The downward movement of clamp 28 is limited by the engagement of clamp shoulders 64 with housing ledges 58, 60. Next, casing 78 may be

applied to flanges 48, 54 and spike 24 may then be inserted into sheath 42. The spike, sheath and tube end are then sterilized by ultraviolet radiation after preferably removing casing 78. During ultraviolet sterilization, spike 24 remains spaced from membrane 11a so that the sterile seal has not been pierced.

After sterilization, the spike 24 is grasped in one hand, housing 44 is grasped in the other hand, and the spike is thrust into tube 11 to puncture membrane 11a. Thereafter casing 78 is positioned about the sheath and spike so as to grasp shoulders 32 and 54, to hold spike 24 in the piercing position.

Then, clamp 28 is retracted to its open position, so that dialysis solution can flow from bag 10 to the patient. After bag 10 is emptied, clamp 28 is thrust downward to again grasp and close tube 11, to close the bag during dialysis solution dwell.

During the dwell phase with solution residing in the peritoneal cavity, the bag and connector may be carried by the patient about his waist. In order to minimize bulk, clamp 28 can be folded about the fold lines as seen in Figures 7 and 8.

When it is necessary to drain the peritoneal cavity, clamp 28 is folded open and slid outwardly so that spent dialysis solution can be drained from the cavity into bag 10. Thereafter, a bag of fresh solution can be exchanged for the bag of spent solution, and the above procedure repeated.

Spike 24 and especially hollow piercing point 38 are preferably made of an ultraviolet-transparent material to permit antimicrobial effect within bore or lumen 29 upon irradiation by a source of ultraviolet light, for example poly(methylpentene), a polyolefin such as polyethylene or polypropylene, EEA(poly(ethylene-ethyl acetate)) or poly(chlorotrifluoroethylene).

Sheath and housing member 26 may be made as a separate item from bag 10 and spike 24, and may be made of a polyolefin such as polyethylene, or other flexible, ultraviolet transparent material such as EEA. Thus the sheath and housing member may be used with different formulations of peritoneal dialysis solution and types of bags, for example. Also, sheath and housing member 26 may be used with currently available bags of peritoneal dialysis solution.

When shoulders 48, 54 are polygonal in shape, and slots 90, 92 in casing 78 are of matching polygonal shape, casing 78 grips member 26 in fixed manner, preventing relative rotation therebetween. This facilitates the installation and removal of tube 11 of container 10 into and from the system, and protects bellows 50.

The above has been offered for illustrative purposes only, and is not intended to limit the scope of the invention of this application, which is as defined in the claims below.

Claims

1. A connector system for making sterilizable connections between a transfer spike (24) on the

end of a transfer tube (19) and a delivery tube (11) closed with a pierceable membrane (11a) and comprising a housing member (26), which includes a collapsible, tubular sheath member (42), at least a portion of which is ultraviolet transparent, an opening (46) in said sheath member at one end of the housing member for receiving the spike, and an opening (61) provided at the other end of the housing member for receiving the delivery tube, the sheath member being expansible and collapsible, to hold the spike in spaced relation to the pierceable membrane in the expanded position and to allow the spike to penetrate the pierceable membrane in the collapsed position, the system being sterilizable by ultraviolet radiation, characterised by clamp means carried by the housing member for retaining and closing the delivery tube, the clamp means including a portion (44) of the housing member (26), which portion defines the opening (61) for receiving the delivery tube (11) and has a transverse channel (56), the clamp means further comprising a slide (28) slidable in the channel, the slide having a slot (72) for receiving the delivery tube (11) and being movable within said channel between tube-closing and tube-opening positions; whereby the delivery tube (11) may be inserted into the sheath member (42) and held in a position to be pierced by moving the slide to the tube-closing position, and said transfer spike (24) may be inserted into the sheath member (42), held for ultraviolet treatment, and then thrust into the delivery tube to pierce the membrane associated therewith and provide a sterile condition.

2. A connector system according to Claim 1, further characterised in that said portion (44) of the clamp means has slide-receiving openings at each end of said channel (56).

3. A connector system according to Claim 2, further characterised in that ledges (58; 60) are provided adjacent each end of the channel engageable with shoulders (64) on the slide (28) for limiting its movement.

4. A connector system according to any one of Claims 1 to 3, further characterised in that the slide (28) comprises a bifurcated, fork-like member having a head section (62) and two leg sections (66, 67), and said leg sections define between them the tube-grasping slot (72) adjacent the head section and a tube-receiving opening (74) more remote from said head section.

5. A connector system according to Claim 4, further characterised in that said slide includes a pair of outwardly-extending hook-like stop members (70) at the end of each leg opposite the head section, said hook-like members being engageable with said portion (44) of the housing member to provide a movement limiting stop.

6. A connector system according to Claim 5, wherein each of said hook-like stop members includes a tapering ramp portion (70a) at the end thereof for cooperation with the channel walls in guiding said slide into the channel.

7. A connector system according to Claim 4, 5

or 6, further characterised in that said slide includes transverse folding lines (65) intermediate the head section (62) and leg sections (66, 67) for permitting said clamp to be folded about said lines.

8. A connector system according to any one of Claims 4 to 7, further characterised in that the outer surface of each of said legs (66, 67) includes a tapered portion (68) intermediate the ends of the slide co-operating with said portions (44) of the housing member to maintain the clamp in a non-grasping position.

9. A connector system according to any preceding claim, further characterised by means (48, 54, 78) for alternatively retaining the transfer spike in piercing and non-piercing positions relative to the container and pierceable membrane.

10. A connector system according to Claim 9, further characterised in that said alternatively retaining means includes:

a pair of spaced first and second shoulder formations (48, 54) defined on said sheath member, with one shoulder formation (48) positioned adjacent the spike-receiving opening (46), and the other (54) positioned between the collapsible portion (50) of the sheath member and said portion (44) of the housing member;

removable retention casing means (78) having a pair of spaced shoulder-grasping ends (87, 88) fixedly spaced from one another, said ends being adapted to grasp the first and second shoulder formations on the sheath member so as to prevent collapsing of the spike-receiving section upon insertion of the spike into the sheath.

11. A connector system according to Claim 10, further characterised in that the transfer spike may also be held in the piercing position by the retention casing means (78) wherein the retention casing means grasps the first shoulder formation (54) on the sheath member adjacent the housing portion (44) and a third shoulder formation (32) on the transfer spike after advancement of the transfer spike through the membrane (11a).

12. A connector system according to Claim 10 or 11, characterised in that said casing means (78) comprises a pair of casing halves (80, 82) connected together in hinged relation.

13. A connector system according to Claim 10, 11 or 12, characterised in that said spaced first and second shoulder formations (48, 54) are of a shape to prevent relative rotation of said sheath member (42) with respect to the retention casing means (78).

14. A connector system according to any preceding claim, characterised in that said transfer spike is transparent to ultraviolet light and is preferably made of poly(methylpentene).

15. A connector system according to any preceding claim, characterised by catheter coupling means (20) at one end of the transfer tube (19) for connection to a patient's catheter (14), with said membrane-piercing transfer spike (24) connected to the other end of the tube.

16. A connector system according to Claim 15,

des Mantels und ein drittes Bundstück (32) auf der Aufstoßnadel aufnimmt nach dem Hindurchführen der Aufstoßnadel durch die Membran (11a).

12. Verbindungssystem nach Anspruch 10 oder 11, dadurch gekennzeichnet, daß die genannte Sicherungsfassung (78) ein Paar Sicherungshälften (80, 82) aufweist, die klappbar miteinander verbunden sind.

13. Verbindungssystem nach Anspruch 10, 11 oder 12, dadurch gekennzeichnet, daß die mit Abstand voneinander angeordneten genannten ersten und zweiten Bundstücke (48, 54) eine Form aufweisen zur Vermeidung einer relativen Drehbewegung des genannten Mantels (42) in Beziehung zur Sicherungsfassung (78).

14. Verbindungssystem nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, daß die genannte Aufstoßnadel für ultraviolette Licht durchlässig ist und vorzugsweise aus Poly(methylpenten) hergestellt ist.

15. Verbindungssystem nach einem der vorhergehenden Ansprüche, gekennzeichnet durch eine Katheterkupplung (20) an einem Ende des Verbindungsschlauches (19) zum Anschließen an einen Patienten-Katheter (14), wobei die genannte die Membran durchstoßende Aufstoßnadel (24) mit dem anderen Ende des Schlauches verbunden ist.

16. Verbindungssystem nach Anspruch 15, gekennzeichnet durch einen Beutel (10) mit einer Dialyselösung, wobei der genannte Beutel mit dem Verbindungsrohr (11) versehen ist.

Revendications

1. Dispositif de connexion pour la réalisation de raccordements stérilisables entre une aiguille de transfert (24) sur l'extrémité d'un tube de transfert (19) et un tube d'alimentation (11) fermé par une membrane perçable (11a), et comprenant un corps extérieur (26) qui comporte un élément (42) de gaine tubulaire écrasable dont au moins une partie est transparente aux ultraviolets, un orifice (46) dans ledit élément de gaine à une extrémité du corps pour recevoir l'aiguille, et un orifice (61) prévu à l'autre extrémité du corps pour recevoir le tube d'alimentation, l'élément de gaine pouvant se dilater ou s'écraser, de manière à maintenir l'aiguille à distance de la membrane perçable dans la position dilatée et à permettre la pénétration de l'aiguille à travers la membrane perçable dans la position écrasée, le dispositif étant stérilisable par un rayonnement ultraviolet, caractérisé par des moyens de serrage portés par le corps pour retenir et fermer le tube d'alimentation, les moyens de serrage comprenant une partie (44) du corps (26), cette partie définissant l'orifice (61) de réception du tube d'alimentation (11) et comportant un canal transversal (56), les moyens de serrage comprenant en outre un coulisseau (28) qui peut coulisser dans le canal, le coulisseau comportant une fente (72) pour recevoir le tube d'alimentation (11) et étant déplaçable à l'intérieur dudit canal entre une position de fermeture du tube et une position d'ouverture du tube; de sorte que le tube d'alimentation (11) peut être inséré dans l'élément de gaine

(42) et tenu dans une position de perçage par déplacement de coulisseau à la position de fermeture du tube, et ladite aiguille de transfert (24) peut être insérée dans l'élément de gaine (42), tenue pour un traitement aux ultraviolets, puis poussée dans le tube d'alimentation pour percer la membrane associée au tube et procurer un état stérile.

2. Dispositif de connexion suivant la revendication 1, caractérisé en outre en ce que ladite partie (44) des moyens de serrage comporte des orifices de réception de coulisseau à chaque extrémité dudit canal (56).

3. Dispositif de connexion suivant la revendication 2, caractérisé en outre en ce que des banquettes (58, 60) sont prévues près de chaque extrémité du canal et elles peuvent entrer en contact avec des saillies (64) prévues sur le coulisseau (28), pour limiter le mouvement de celui-ci.

4. Dispositif de connexion suivant l'une quelconque des revendications 1 à 3, caractérisé en outre en ce que le coulisseau (28) est une pièce fourchue comportant une partie de tête (62) et deux branches (66, 67), et lesdites branches définissent entre elles la fente (72) de serrage de tube, près de la tête, et un orifice (74) de réception de tube, plus éloigné de ladite tête.

5. Dispositif de connexion suivant la revendication 4, caractérisé en outre en ce que ledit coulisseau comporte deux éléments de butée (70) en forme de crochet s'étendant vers l'extérieur, à l'extrémité de chaque branche et à l'opposé de la tête, lesdits éléments en forme de crochet pouvant venir en contact avec ladite partie (44) du corps pour constituer une butée de limitation du mouvement.

6. Dispositif de connexion suivant la revendication 5, dans lequel chacun desdits élément de butée en forme de crochet comporte une rampe inclinée (70a), à son extrémité, qui coopère avec les parois du canal pour guider ledit coulisseau dans le canal.

7. Dispositif de connexion suivant la revendication 4, 5 ou 6, caractérisé en outre en ce que ledit coulisseau comporte des lignes de pliage transversales (65) entre la tête (62) et les branches (66, 67) pour permettre un pliage de ladite pince suivant lesdites lignes.

8. Dispositif de connexion suivant l'une quelconque des revendications 4 à 7, caractérisé en outre en ce que la surface extérieure de chacune desdites branches (66, 67) comprend une partie inclinée (58) entre les extrémités du coulisseau, qui coopère avec ladite partie (44) du corps pour maintenir la pince dans une position de non serrage.

9. Dispositif de connexion suivant l'une quelconque des revendications précédentes, caractérisé en outre par des moyens (48, 54, 78) pour retenir sélectivement l'aiguille de transfert dans des positions de perçage et de non-perçage, par rapport au récipient et à la membrane perçable.

10. Dispositif de connexion suivant la revendication 9, caractérisé en outre en ce que lesdits moyens de retenue sélective comprennent:

une première et une deuxième collerettes espacées (48, 54) définies sur ledit élément de gaine, une collerette (48) étant située près de l'orifice (46) de réception d'aiguille, et l'autre collerette (54) étant située entre la partie écrasable (50) de l'élément de gaine et ladite partie (44) du corps;

un boîtier de retenue amovible (78) comportant deux extrémités espacées de serrage de collerette (87, 88), espacées l'une de l'autre de façon fixe, lesdites extrémités étant prévues pour saisir les première et deuxième collerettes de l'élément de gaine de manière à empêcher l'écrasement de la partie de réception d'aiguille lors de l'insertion de l'aiguille dans la gaine.

11. Dispositif de connexion suivant la revendication 10, caractérisé en outre en ce que l'aiguille de transfert peut également être maintenue dans la position de perçage par le boîtier de retenue (78), le boîtier de retenue serrant la première collerette (54) de l'élément de gaine, adjacente à la partie de corps (44), et une troisième collerette (32) prévue sur l'aiguille de transfert, après l'avance de l'aiguille de transfert à travers la membrane (11a).

12. Dispositif de connexion suivant la revendication 10 ou 11, caractérisé en ce que ledit boîtier

(78) comprend deux demi-boîtiers (80, 82) reliés l'un à l'autre de façon pivotante.

13. Dispositif de connexion suivant la revendication 10, 11 ou 12, caractérisé en ce que lesdites première et deuxième collerettes espacées (48, 54) ont une forme qui empêche la rotation relative dudit élément de gaine (42) par rapport au boîtier de retenue (78).

14. Dispositif de connexion suivant l'une quelconque des revendications précédentes, caractérisé en ce que ladite aiguille de transfert est transparente à la lumière ultraviolette et est de préférence fabriquée en poly(méthylpentène).

15. Dispositif de connexion suivant l'une quelconque des revendications précédentes, caractérisé par des moyens de raccordement de cathéter (20) prévus à une extrémité du tube de transfert (19), pour le raccordement au cathéter d'un patient, ladite aiguille de transfert (24) pour le perçage de la membrane étant connectée à l'autre extrémité du tube.

16. Dispositif de connexion suivant la revendication 15, caractérisé par un sac (10) de solution de dialyse, ledit sac comportant le tube d'alimentation (11).

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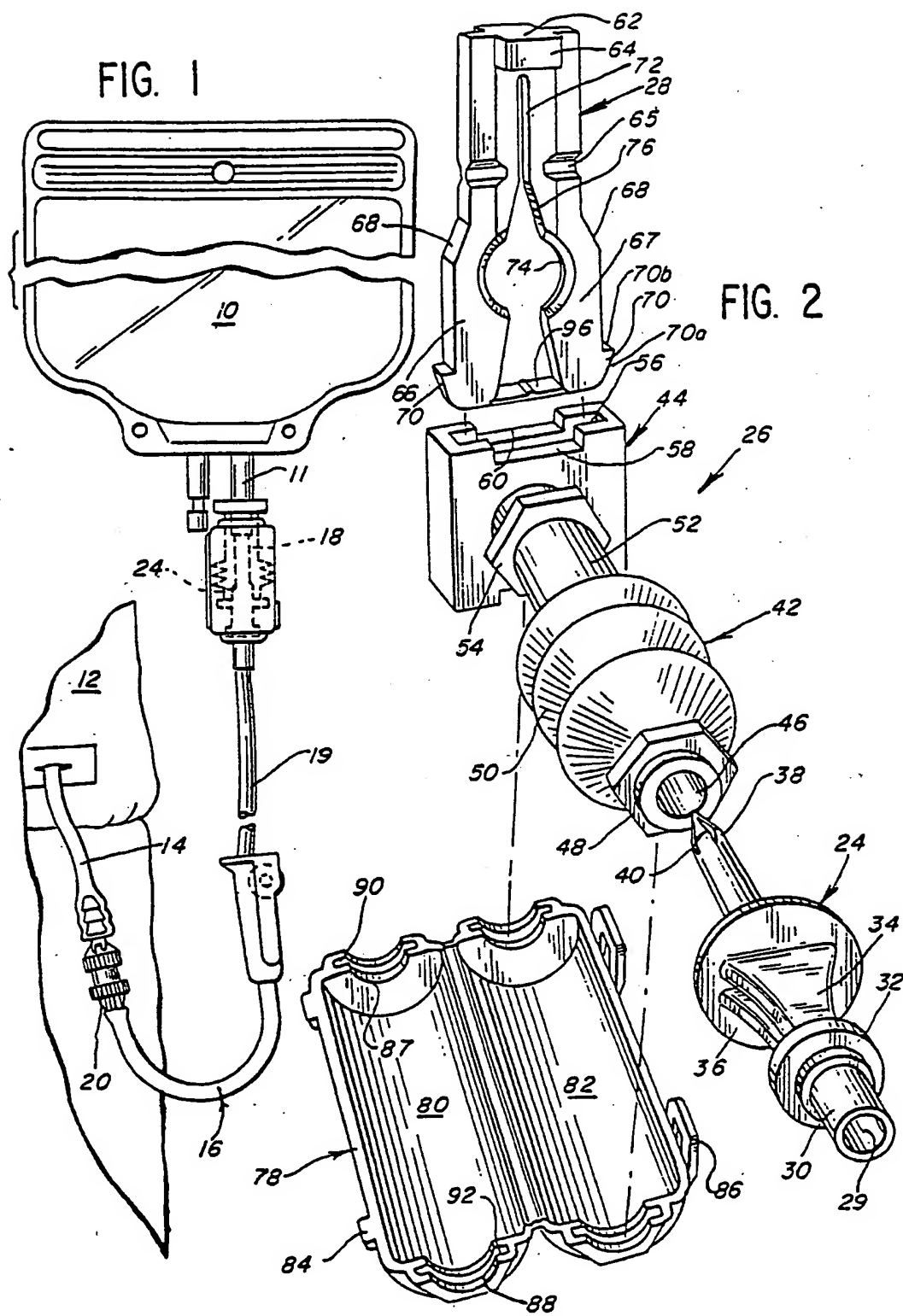
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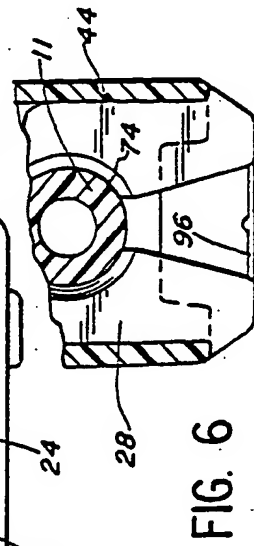
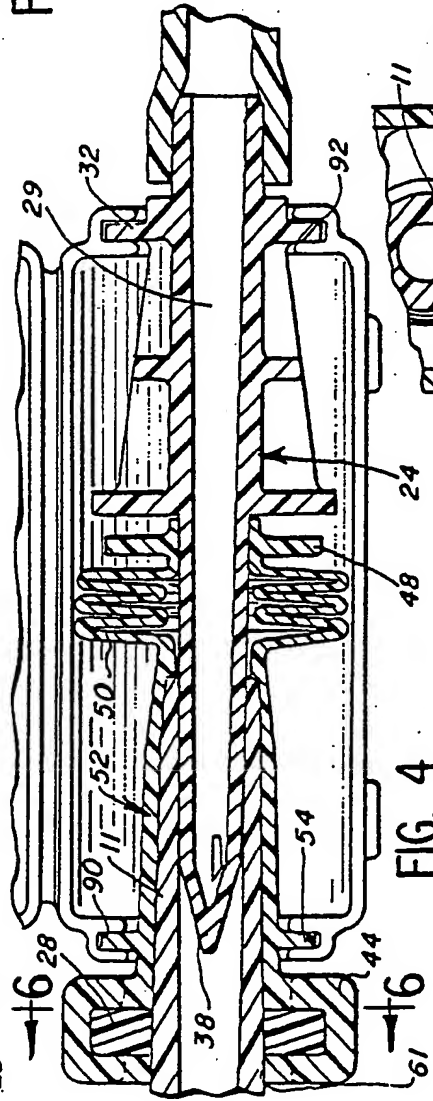
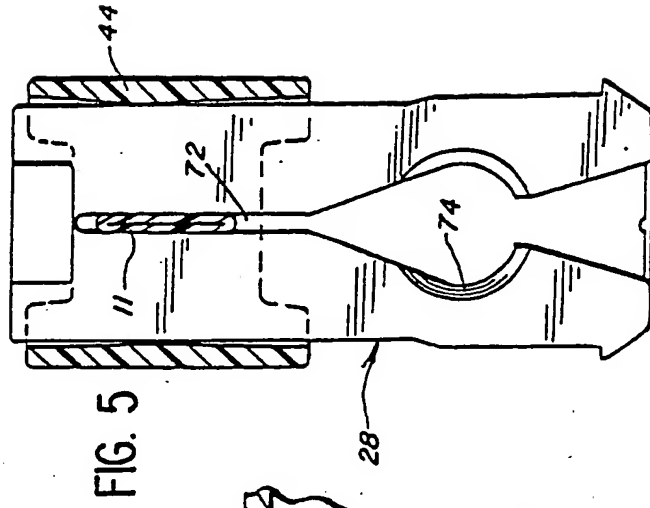
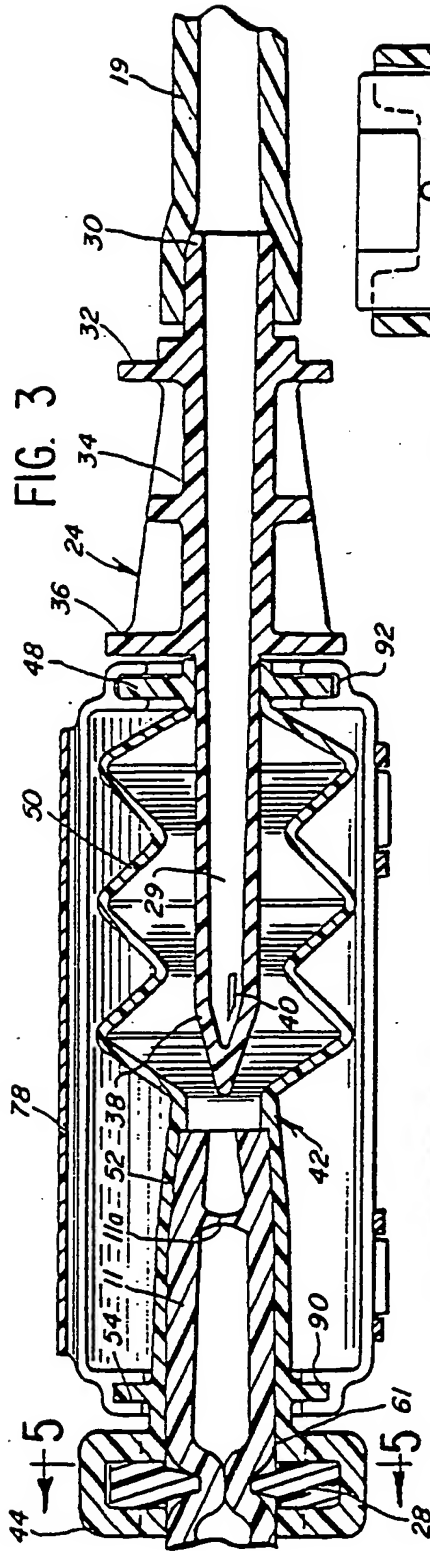
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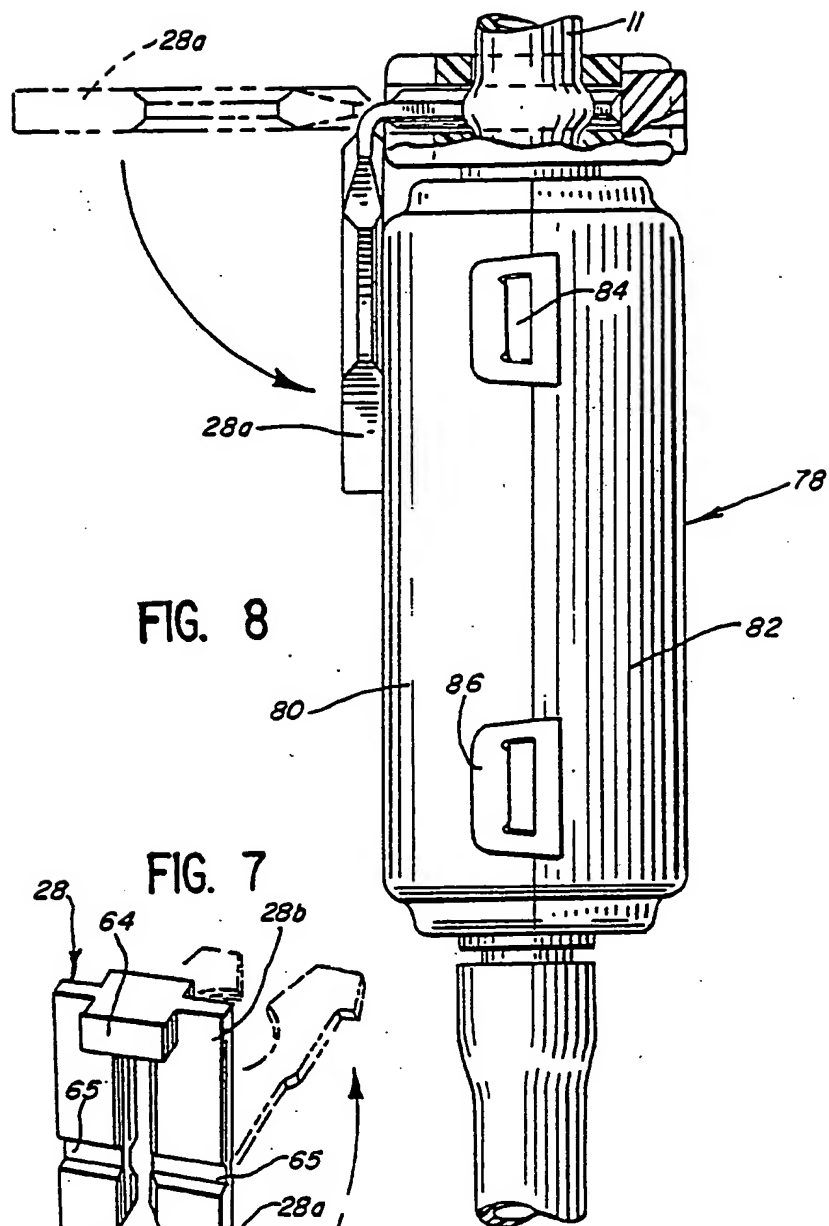


FIG. 8

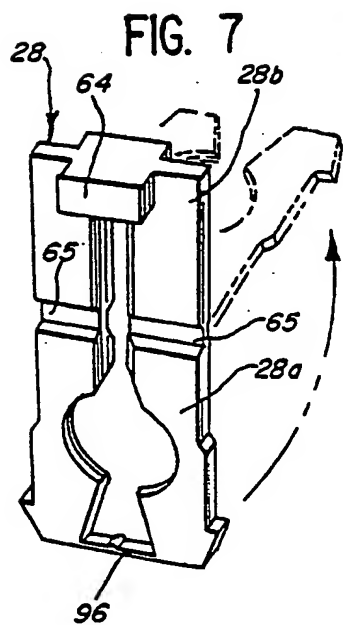


FIG. 7